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RECORD OF ORAL HEARING

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JEFFREY HUBBELL, JASON SCHENSE,
ANDREAS ZISCH, HEIKE HALL

Appeal 2010-004497
Application 10/650,509
Technology Center 1600

Oral Hearing Held: May 12, 2011

Before ERIC B. GRIMES, FRANCISCO C. PRATS, and
JEFFREY N. FREDMAN, *Administrative Patent Judges.*

APPEARANCES:

ON BEHALF OF THE APPELLANT:

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The above-entitled matter came on for hearing on Thursday, May 12, 2011, commencing at 9:58 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before John Hutson.

PROCEEDINGS

THE USHER: Calendar No. 41, Appeal No. 2010-4497, Ms. Monheit.

JUDGE GRIMES: Good morning, Ms. Monheit.

MS. MONHEIT: Good morning.

JUDGE GRIMES: As you know, you'll have 20 minutes to make your argument. Start when you're ready. And if you wouldn't mind introducing your colleague for the record.

MS. MONHEIT: That's what I was about to do. I'd like to introduce my colleague, Dr. Yvonne Shyntum, who is also a patent agent who works with our firm and is familiar with this case as well.

So we're here regarding an appeal, Appeal No. 2010-004497, which is regarding serial number 10/650,509. The only rejections on appeal regard obviousness-type double-patenting. Now there are two rejections over the '422 patent and '740 patent that we're not disputing, that we've offered to file total disclaimer once the claims are otherwise determined to be patentable, so we weren't planning to discuss those today.

We have two remaining -- patenting rejections. One is over this patent number 7247609, which is owned by ETH and University of Zurich, and the other one was is over U.S. Serial No. 10/323, 046 which has since issued at U.S. Patent No. 7601685 and issued on October 13th, 2009. Just

want to be sure that you already have those claims because we didn't discuss them in the Appeal before -- because they changed just a little bit.

Again, both of those patents are owned by a different entity. They're owned by ETH and University of Zurich, and our Application is owned by CalTech. Our primary argument is that obviousness-type -- patent rejections should not be made when different -- on development application and the second patent, even if there's a common inventor.

JUDGE FREDMAN: That argument is for *In Re: Fallaux* by the Federal Circuit. *In Re Fallaux* they pretty much addressed that.

MS. MONHEIT: And actually, I like that you've brought up *In Re: Falu* because I was planning to bring it up as well. *In Re Fallaux*, which is a cite that apparently you all have, which is 564, F.3rd, 1313. It's a 2009 case by the Federal Circuit, had a similar fact scenario. It also was a double-patenting analysis in which they had two different owners. In that particular case under those facts, the Federal Circuit determined that the Appellant delay precluded a two-way obviousness-type double-patenting analysis.

I think that our Application is different, but before going through that analysis I also want to point out a footnote in that case which I thought was a green light to our argument today, where the Federal Circuit says "Neither party raised nor argued whether a patent may be used as a reference for obviousness-type double-patenting where the patent shows only a common inventor, rather than identical inventor -- this opinion should not be held to decide or endorse the -- on this issue." I mean, it's a gratuitous footnote that I think is dealing with the exact issue that we're dealing with today, which is what is the equity --

JUDGE FREDMAN: There's a balance of equity between -- and the inability essentially of you to file the -- disclaimer.

MS. MONHEIT: Exactly. And this case law that's come out, you know, started in pre-GATT case law to create this equity where we promote sharing of incremental inventions in the form of CIPs but don't grant extra patent term. Okay, the perfectly solution was these total disclaimers. But now we've come into some very interesting situations where what happened here, we have one inventor who moves institutions. Why should the fact that Jeff Hubbell moves from CalTech to the University of Zurich make a difference as to whether or not he gets a patent for the same incremental invention because of patent policy that has evolved in view of pre-GATT cases?

JUDGE GRIMES: So I take it your position would be that *Van Ornum* is distinguished on that basis as a pre-GATT --

MS. MONHEIT: I would -- I have to pull up *Van Ornum*. It's a pre-GATT case, so -- I'm sorry?

JUDGE GRIMES: I think *Van Ornum* has the same situation.

MS. MONHEIT: Yes, I do think that the pre-GATT situation plays a strong role in whether or not we should be analyzing a claim over -- or not. In this particular case when we look at the equity of the situation of -- we would have no diminished patent term even if -- we'd be happy to file total disclaimer if we could. Patent Office policy has made it difficult for us to do that because we don't have the same -- even if we filed total disclaimer, we wouldn't be giving up any patent term, which is, you know, again why it wouldn't make a difference. Again to distinguish -- just one more point to

address your initial question about *Fallaux* and again this equity issue, in *Fallaux* the -- I believe this was, you know, Column 5 or 6 where basically they held that applicant delay really prevented the use of a two-way obviousness-type double-patenting analysis.

Well, in our case, while one could claim there is some level of Applicant delay, there's also, of course, Patent Office delay that's occurred, and in 2003 we presented these claims. And in our first Office Action on the Merits in 2006, the Examiner misread our priority claim, so we got bogged down in dealing with an issue to convince the Examiner that we were -- that we had a priority claim and therefore -- in 2006 if you would've read out priority claim properly, all we would've had was an obviousness-type double-patenting rejecting. We would be at the state where we are now.

At that point, we had these two now-patents. The '609 and the '685 patents were pending applications. We would've then been able to say okay, you know what, why don't you let our patent issue; we'll file a total disclaimer; and should you want to raise these rejections in the other pending applications, we'll deal with them there, and we wouldn't be here today. So we do also have an element of Patent Office delay that's playing into bringing us here today in 2011 for a case that was filed in 2003 with the same claims that we have today.

JUDGE FREDMAN: But you didn't really argue that in your briefing, correct?

MS. MONHEIT: No, I didn't argue that we should be entitled to a two-way obviousness-type double-patenting analysis, but I think the -- we argued that this is wrong. I think there are lots of different ways that this can

be solved, especially in view of the fact that this is all judge-made case law that is applied in different ways at different times by the Patent Office, and I think that there is leeway for the Patent Office to either say you know what, in this case, yes, there is Patent Office delay; okay, let's apply the two-way patenting -- double-patenting rejection or let's look at what's happened, you know, in 2004 with the CREATE Act. Again, the Patent Office, because of certain legislation that came down, has created a way for different assignees in a limited situation, where there's a joint research agreement, to file total disclaimer, even though they're not co-assignees. Well, the Patent Office could extend that and say okay, well, even if you don't have the same assignee, we could use the same kind of a -- same structure to deal with this type of situation.

JUDGE FREDMAN: One question just very specifically on the '609 patent. The parathyroid hormone, are you calling that a growth factor, or is parathyroid hormone not a growth factor?

MS. MONHEIT: It's not a growth hormone.

JUDGE FREDMAN: So you're saying that that one is also separate because it doesn't have a growth factor?

MS. MONHEIT: That one is also separate because it doesn't have a growth factor.

JUDGE FREDMAN: So there's apparently the double-patenting.

MS. MONHEIT: We could also argue on the merits, as we did in the Appeal Brief and in the Reply Brief, that with respect to specifically the '609 patent, that does not contain a growth factor.

JUDGE FREDMAN: Right.

MS. MONHEIT: It also has the enzymatic degradation site, I believe.

JUDGE FREDMAN: That's a comprising issue, but --

MS. MONHEIT: The growth factor is different. The Examiner noted that in the original election of species requirement when the Examiner was looking at this particular case that --

JUDGE FREDMAN: But for the '685 one, I don't think that option exists.

MS. MONHEIT: No, it does not. We have two growth factors there.

JUDGE FREDMAN: Right.

MS. MONHEIT: That's specifically listed, that's correct.

JUDGE FREDMAN: Right.

JUDGE PRATS: Why doesn't *Van Ornum* foreclose the argument about separate ownership?

MS. MONHEIT: Let me flip to my copy of *Van Ornum.*

JUDGE PRATS: Isn't the Board constrained by *Van Ornum* to basically affirm -- at least not buy into that argument --

MS. MONHEIT: Well, the Federal Circuit -- I'm sorry?

JUDGE FREDMAN: We're concerned in a way the Federal Circuit is not, of course.

MS. MONHEIT: Okay. So the Federal Circuit didn't feel that you were. I think I would continue to rely on the pre-GATT status of *Van Ornum* versus the post-GATT status of where we are, where the fact that it would -- that the equity of granting a patent would then have a longer patent terms because it issued later would play into the analysis of whether or not you need a total disclaimer to deal with that situation. And in our case, it

just -- it creates an inequity because of the situation we are not being granted any extra patent term by granting this patent. We're not creating an extension of a monopoly.

JUDGE FREDMAN: But you are perhaps giving two different assignees the ability to -- in other words, if this were to issue, you could have CalTech and the University of Zurich suing somebody instead of requiring just a single assignee. So you would have sort of a harassment by multiple assignees.

JUDGE PRATS: And that's the rationale in *Van Ornum*. That's why my concern is that we can't reverse for that reason because *Van Ornum* says we can't.

MS. MONHEIT: Right, but the Patent Office has since *Van Ornum* in 2004 created a method to deal with this, which is to allow --

JUDGE FREDMAN: To indicate that there's a joint research agreement.

JUDGE PRATS: Right.

JUDGE FREDMAN: You don't have that, right?

MS. MONHEIT: But I mean, even that did not exist at the time that Van Ornum was decided. That whole concept has evolved.

JUDGE PRATS: Although, technically, the CREATE Act doesn't address this issue because we only have --

MS. MONHEIT: Right. Exactly. It would be an extension. But I do think that if -- I think the second way in which the Patent Office has dealt with situations that are similar to this one is to use the two-way obviousness-type double-patenting analysis. You know, in preparing for this oral

hearing, I've been thinking a lot about the patent policy and the equity and balancing, and there's a -- I think even the MPEP sites do. In this obviousness-type double-patenting analysis, there's a 1992 Federal Circuit case where they talk about well, even if you filed the SIP after -- that was not considered, you know, sufficient applicant delay to prevent using the two-way analysis. So there's definitely this balancing act that the Patent Office can apply in deciding to use the two-way obviousness-type double-patenting analysis.

And by analogy, in the context of an Interference, what happens? You have two different parties, and in determining whether or not there's an interference in fact you look at a two-way obviousness-type double-patenting analysis to determine whether or not -- and if one doesn't exist, you get two patents.

JUDGE FREDMAN: But the two-way test, though, would be hard for you because these cases both go back -- your case goes back to '97. There's a common value of the PCT, and then the CIP which issues the patent, and then the Kahn (ph) and the Hubbell patent goes back to '98 and was filed in 2000 and then the CIP. So, I mean, there's a lot of prosecution here. This isn't a situation where the PTO prevented you from presenting these claims way back in 1998 or whatever it would've been when you had the first case.

MS. MONHEIT: But we couldn't have presented them in 1998. The earliest point that we could have presented them is when we filed that CIP, which is in 2001.

JUDGE FREDMAN: Okay. But still, there's a lot of prosecution relatively early, too.

MS. MONHEIT: And this is why I think we'd go into the balancing act of looking -- we filed these claims in 2003. They haven't changed in any substantive way. The scope hasn't changed in any substantive way since then. In 2006, the Examiner misanalyzed our priority claim and we wound up talking about something that was -- would have normally been an irrelevant topic, and we could have -- you know, but for this, you know, being sidetracked about a priority claim that was clear on its face, could have been in a situation where the Examiner could have allowed this case easily. So the PTO shares responsibility. I'm not saying that we're blameless. I'm just saying that there is shared responsibility. The question is where do the equities put us? Are we trying to prevent inventors from moving from one institution to another and continuing on in their research? I mean, these are exactly the kinds of things that the CREATE Act was talking about. Why should we penalize -- I keep trying to get my head around why should it make a difference that our inventor moved from one institution to another and continued to do his research and that, therefore, we have a disparate result.

The MPEP seems to be laying out a framework where in most cases it has a solution. You can get your patent. Either it's prior art and then okay, we go through a prior art analysis . Well, if we do a prior art analysis, we still get our patent. But that's not our situation here. In other situations, we have a common owner. We can filed total disclaimer, we can get our patent. Unfortunately, because of the way the case law has evolved and the changes

in policy, we have this hole where -- the situation where an inventor moves and continues his research has created the inability to get a patent.

JUDGE FREDMAN: Which happens -- really. No one's at fault, but ultimately that was the unfortunate result in that case as well -- also didn't get his patent.

MS. MONHEIT: Right. And the Federal Circuit has said -- I believe the Federal Circuit is giving a guideline to say --

JUDGE FREDMAN: Maybe.

MS. MONHEIT: The Federal Circuit has placed a gratuitous footnote in *Fallaux* saying we're starting to see that this is a problem. I think they're acknowledging this problem and saying that there are ways to deal with this problem that are equitable, and we can -- in this particular case, without changing any policy, we can apply the two-way obviousness-type double-patenting analysis. I think that there is a basis for that. It was in the file -- for this case. Or we can say that there are mechanisms already within the Patent Office that we can extend to these types of situations. And again, we can acknowledge that a hormone is not a growth factor.

JUDGE FREDMAN: The parathyroid hormone is not.

MS. MONHEIT: Thank you, the parathyroid is not a growth factor.

JUDGE FREDMAN: Some hormones are growth factors.

JUDGE GRIMES: Did you have anything else?

MS. MONHEIT: No. I thank you very much for your time.

JUDGE GRIMES: Thank you.

(Whereupon, the proceedings, at 10:15 a.m., were concluded.)